UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

---

R.S.B., a minor, by and through his Parent and Next Friend, Stephanie Hammar, and STEPHANIE HAMMAR, Individually,

Plaintiffs,

v. Case No. 20-C-1402

MERCK & CO., INC. and MERCK SHARP & DOHME CORP.,

Defendants.

---

**DECISION AND ORDER DENYING DEFENDANTS' MOTION FOR PARTIAL DISMISSAL**

---

Plaintiffs R.S.B., a minor, and Stephanie Hammar brought this action against Defendants Merck & Co., Inc., and Merck Sharp & Dohme Corp., alleging that R.S.B.'s use of Defendants' product Singulair® caused him to suffer neuropsychiatric injuries. Plaintiffs assert claims of strict liability design defect, strict liability failure to warn, and negligence. This matter comes before the Court on Defendants' motion for partial dismissal under Federal Rule of Civil Procedure 12(b)(6) seeking to dismiss Plaintiffs' design defect claim. Alternatively, Defendants seek a more definite statement pursuant to Rule 12(e). For the following reasons, Defendants' motion will be denied.

## LEGAL STANDARD

A Rule 12(b)(6) motion tests the sufficiency of the complaint to state a claim upon which relief can be granted. *Gibson v. City of Chicago*, 910 F.2d 1510, 1520 (7th Cir. 1990); *see* Fed. R. Civ. P. 12(b)(6). When reviewing a motion to dismiss under Rule 12(b)(6), the court must accept

all well-pleaded factual allegations as true and draw all reasonable inferences in the light most favorable to the nonmoving party. *Gutierrez v. Peters*, 111 F.3d 1364, 1368–69 (7th Cir. 1997); *Mosley v. Klincar*, 947 F.2d 1338, 1339 (7th Cir. 1991).

In order to survive a Rule 12(b)(6) motion to dismiss, a complaint must include factual allegations that are sufficient "to raise the right of relief above the speculative level." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). "[T]he pleading standard Rule 8 announces does not require 'detailed factual allegations,' but it demands more than an unadorned, the defendant-unlawfully-harmed-me accusation." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 540 U.S. at 555). "[A] complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face,'" and those facts must be adequate to allow the court to infer that "the defendant is liable" for the harm. *Id*. (quoting *Twombly*, 540 U.S. at 570).

Rule 12(e) provides that "[a] party may move for a more definite statement of a pleading to which a responsive pleading is allowed but which is so vague or ambiguous that the party cannot reasonably prepare a response." Fed. R. Civ. P. 12(e). "Motions under Rule 12(e) are disfavored generally, and courts should grant such motions only if the complaint is so unintelligible that the defendant cannot draft a responsive pleading." *Rivera v. Lake Cty.*, 974 F. Supp. 2d 1179, 1195 (N.D. Ill. 2013) (citation omitted).

**ALLEGATIONS CONTAINED IN THE SECOND AMENDED COMPLAINT**

Plaintiff R.S.B. was prescribed Singulair to treat his asthma and hay fever symptoms from December 2010 to August 2012. 2d Am. Compl. ¶ 7, Dkt. No. 29. Plaintiffs allege that, as a direct and proximate result of ingesting Singulair, R.S.B. was admitted to Bellin Psychiatric Center's inpatient facility for suicidal and homicidal thoughts and was ultimately diagnosed with Major

Depressive Disorder; Anxiety Disorder; Obsessive-Compulsive Disorder; Ego-Dystonic; intrusive thoughts about homicidal, suicidal, and sexual thoughts; and poor coping. *Id.* ¶ 8. They assert that these neuropsychiatric events are identical or akin to those now included on Singulair's warning label. *Id.* Plaintiffs claim that R.S.B.'s symptoms worsened after August 2012 due to the latent effect of Singulair. *Id.* ¶ 10. Plaintiffs allege that, after August 2012, R.S.B. began using generic montelukast, the active ingredient in Singulair, and that he suffered more severe injuries as a result of the cumulative effect of using Singulair and then generic montelukast. *Id.* ¶¶ 11, 20.

Defendants discovered the anti-asthmatic properties of montelukast and were granted U.S. Patent No. 5,565,473 in 1996. *Id.* ¶ 20. Defendants were the exclusive manufacturers, distributers, and sellers of Singulair. *Id.* ¶ 13. Singulair (montelukast) has become a ubiquitous monotherapy treatment as an alternative to, and as an add-on therapy to, inhaled corticosteroids, such as fluticasone, to stop asthma and allergy symptoms. *Id.* ¶¶ 21, 24. Although generic manufacturers of montelukast entered the market when Defendants' patent expired in 2012, Defendants have maintained control of the brand name Singulair. *Id.* ¶ 13. Approximately 9.3 million patients received a montelukast prescription for United States outpatient pharmacies in 2018, with 2.3 million of these patients being children younger than 17 years old. *Id.* ¶ 21.

Plaintiffs assert that montelukast crosses the blood-brain barrier (BBB), which is a semi-permeable membrane of endothelial cells that is highly selective in preventing solutes in circulating blood from non-selectively entering the extracellular fluid and thereby interacting with neurons in the central nervous system. *Id.* ¶ 25. The BBB's purpose is to protect the brain from circulating pathogens and render bloodborne brain infections rare. No antibodies, only certain antibiotics, and exceedingly few drugs may pass the BBB and have an impact on the central nervous system. *Id.* ¶ 26. Plaintiffs allege that, because montelukast crosses the BBB, it exerts a

systemic effect upon the central nervous system that results in adverse neuropsychiatric events, among other things. *Id.* ¶ 31. They claim that the risk of new neuropsychiatric events is greater in pediatric patients who take Singulair. *Id.* ¶ 38. Plaintiffs allege that Defendants knew montelukast could affect the brain at least by 1996. *Id.* ¶ 44. In 2020, after reviewing adverse event data involving montelukast, the Food and Drug Administration (FDA) required Defendants to add a black box warning related to the risk of mental health side effects. *Id.* ¶¶ 47–48. Plaintiffs assert claims of strict liability design defect, strict liability failure to warn, and negligence against Defendants.

**ANALYSIS**

Defendants assert that Plaintiffs have failed to allege sufficient facts to support their strict liability design defect claim. Section 895.047 of the Wisconsin Statutes provides, in relevant part, that a manufacturer is strictly liable for a defect in design "if the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the manufacturer and the omission of the alternative design renders the product not reasonably safe." Wis. Stat. § 895.047(1)(a). Defendants assert that Plaintiffs have failed to adequately plead that a reasonable alternative design exists.

Plaintiffs assert that Singulair suffers from design defects that could have been reduced or avoided by the adoption of two proposed reasonable alternative designs. First, Plaintiffs assert that modifications to montelukast that decrease its ability or propensity to cross the BBB would have made it safer. 2d Am. Compl. ¶ 71. They allege that numerous other pharmaceutical products with indications similar to those of Singulair that do not cross the BBB exist and propose a version of Singulair similar to an inhaled corticosteroid that would not "have the same propensity to cross the blood-brain barrier." *Id.* ¶¶ 72–73. Plaintiffs summarize their first proposed alternative design

as "simply a tablet that does not permit the active ingredient to infiltrate the brain" and that would not have caused an increased risk of neuropsychiatric events. Pls.' Resp. Br. at 2, Dkt. No. 33; 2d Am. Compl. ¶ 75.

Plaintiffs' second proposed alternative design are tablets and granules of Singulair in doses lower than 4 milligrams, the lowest base dose of Singulair currently available. *See* 2d Am. Compl. ¶ 80. Plaintiffs allege that Singulair is and at all relevant times has been available in EQ 4 milligrams base (granules), EQ 4 milligrams base (tablet), EQ 5 milligrams base (tablet), and EQ 10 milligrams base. *Id.* ¶ 78. Plaintiffs assert that, although Defendants recognized a difference in safety and/or efficacy in 1 milligram increments by designing, testing, marketing, and selling a 4 milligram base and a 5 milligram base, Defendants did not make a 1 milligram base available. *Id.* ¶ 79. They explain that offering 4 milligrams as the lowest available dose unnecessarily forces doctors to prescribe Singulair "in higher doses than where required for efficacy" and thus the tablets and granules packages are defectively designed. *Id.* ¶ 79. Plaintiffs allege that reasonable alternative designs in the dosing of Singulair were available to Defendants during all relevant times and that "Defendants could have designed Singulair tablets and granules packages in lower doses, which would have been a safer design." *Id.* ¶¶ 76, 80.

Citing *Nelson v. Johnson & Johnson*, 428 F. Supp. 3d 1 (E.D. Wis. 2019), Defendants assert that Plaintiffs' design defect claim must be dismissed due to Plaintiffs' failure to properly plead and inability to prove that a safer product design exists and would be approved by the FDA. But Defendants' reliance on *Nelson* is misplaced. *Nelson* addressed the issue of whether § 895.047 was to apply retroactively; it did not address pleading requirements. There, the court explained:

> Section 895.047 of the Wisconsin Statutes altered the way in which a plaintiff proved a strict products liability claim. It essentially changed the elements. As an initial matter, the statute redefines a defectively-designed product. Rather than defining a defectively designed product as one where the design itself is the cause

> of the unreasonable danger, the statute provides that "[a] product is defective in design if the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the manufacturer and the omission of the alternative design renders the product not reasonably safe." Wis. Stat. § 895.047(1)(a). Implicit in this new language is the rule that an inherently dangerous product for which there is no safer alternative cannot be found unreasonably dangerous. Section 895.047(1)(a) thus imposes new burdens on a plaintiff by requiring that she prove foreseeability and that a reasonable alternative design exists and should have been adopted by the manufacturer. Where there are no safer alternatives, it deprives her of her right to recover, even though the product is unreasonably dangerous.

*Id.* at 5 (alterations in original). Although § 895.047 altered the way in which a plaintiff must prove a strict products liability claim, the statute does not place an increased factual pleading burden upon a plaintiff claiming a design defect under Wisconsin law. A plaintiff is not required to prove every element of the claim alleged to survive a motion to dismiss; all that is required is that the plaintiff give "fair notice of what the . . . claim is and the grounds upon which it rests." *Twombly*, 550 U.S. at 555. Plaintiffs have adequately alleged the existence of alternative designs, and their allegations are not so vague as to fail to provide notice to Defendants. Whether there is any substance to Plaintiffs' design defect claim is a matter for discovery and can be resolved on summary judgment. Therefore, Defendants' motion to dismiss and for a more definite statement is denied.

## CONCLUSION

For these reasons, Defendants' motion to dismiss count one (design defect) of Plaintiffs' second amended complaint and for a more definite statement (Dkt. No. 30) is **DENIED**.

**SO ORDERED** at Green Bay, Wisconsin this 7th day of May, 2021.

s/ William C. Griesbach
William C. Griesbach
United States District Judge